

Maryland Board of Pharmacy
Public Minutes
August 22, 2007

Officers Present: Donald Taylor, Acting President

Commissioners: Cynthia Anderson, David Chason, Harry Finke, Jr., Mayer Handelman, Lenna Israbian-Jamgochian, Alland Leandre, Rodney Taylor, Reid Zimmer, and Michael Souranis

Commissioners Absent: Lynette Bradley-Baker and Margie Anne Bonnett

Board Staff: LaVerne Naesea, Executive Director; Patricia Gaither, Administrative and Public Support Manager; Summar Goodman, Public Information Officer; Tamarra Banks, MIS Manager; Vanessa Thomas-Gray, Compliance Investigator; Colin Eversley, Compliance Investigator; Steven Kreindler, Compliance/Health Services Coordinator; Shirley Costley, Licensing Specialist; and Fedelyne Dieuyuste, Intern, University of Maryland School of Pharmacy

Board Counsel: Linda Bethman

Guests: Howard Schiff, MPhA; Roopa Pastaksa, Target; Georgette Zoltani, Division of Drug Control; Justin Coyle, Walgreens; Gilbert Cohen, PEAC; Melike Tunc, Student, University of Maryland School of Pharmacy; and Stanton Ades, NACDS

I. Introduction/Recusals- Members of the Board with a conflict of interest relating to any item on the agenda were asked to notify the Board at this time. There were no recusals.

II. Approval of Minutes July 18, 2007

Page 3 – paragraph 8 – 2nd sentence, delete the word “Thursday” and add the word “July”.

Page 3 – Under the 2nd Motion, 2nd sentence, delete the word “interested”.

Page 6 – Under Pharmacy Technician Database – 1st sentence, delete the word “has” and add the word “have”.

Page 9 – Under C – Long Term Care Task Force, 2nd sentence insert “Assisted Living” before “patients who receive nine (9) or more medications”.

Motion: Harry Finke, Jr. moved to accept the minutes as amended. Rodney Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

III. President/Executive Committee Report – Donald Taylor

Introduction of New Board Members

Mr. Taylor introduced new Board Commissioners Lenna Israbian-Jamgochian, appointed to the chain pharmacy position and Reid Zimmer, appointed to the acute care hospital position.

Inspection Transition Plan

Mr. Taylor reported that the Board and the Division of Drug Control (DDC) met to finalize the proposed transition plan regarding the Board assuming responsibility for conducting its own opening and annual pharmacy inspections. The Division of Drug Control has been designated as the Board’s agent to perform inspections of all in-state pharmacies annually. The proposed transition plan will be submitted to the DHMH Secretary in August. Once the proposal has been approved by the Secretary, the Board will move forward with the timeline reflected in the transition plan. Specifically, DDC would perform administrative, closing inspections and related CDS inspections. The Board of Pharmacy would conduct opening and routine inspections. There may be occasions for both units to perform coordinated inspections, particularly in relation to joint investigations. All inspection reports will be shared through the shared database system. The target date for the transition is January 2008. Mr. Taylor asked the Board for approval of the “Division of Drug Control Proposed Transition Plan “ as presented.

Motion: Harry Finke, Jr. moved to accept the “Division of Drug Control Proposed Transition Plan”. Rodney Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

A pharmacist inspector will be hired to provide oversight of non-pharmacist inspectors and will also perform inspections. Approximately twenty-five (25) inspections would be conducted by each inspector per month. Initially, inspectors would be performing pharmacy inspections by regions. Once the plan is approved by the Secretary, the transition plan will be posted on the (public information) website.

Election of Officers

Elections for new Board Officers were conducted. Cynthia Anderson asked that her name be removed from the ballot for the office of secretary. David Chason requested to have his name removed from the ballot for the office of treasurer and nominated Ms. Anderson for the position of treasurer. The final ballot consisted of President: Donald Taylor; Secretary: David Chason; and Treasurer: Rodney Taylor, Michael Souranis and Cynthia Anderson .Election Results:

President – Donald Taylor;
Secretary – David Chason; and
Treasurer – Michael Souranis

IV. Executive Director’s Report – LaVerne Naesea

Introduction of New Board Members

Ms. Naesea welcomed the new Board Commissioners, and also introduced Fedelyne Dieuyuste, an intern from the University of Maryland School of Pharmacy. Ms. Dieuyuste will complete a four (4) week rotation with the Board of Pharmacy.

Ms. Naesea reviewed the Board’s Action Item Chart, noting that action items at the bottom portion of the first page had been completed. Ms. Naesea explained that additional action items are voted on at each Board meeting. The chart will be updated monthly to show the status of each assignment.

Action Item: Summar Goodman will provide notice in the Fall newsletter requesting pharmacists to update their e-mail addresses.

Prescription Repository Grant

Ms. Naesea stated that the Board has \$25,000 in its’ budget to provide grants and requested that the Board consider awarding \$25,000 to MedBank to provide start-up support as the primary repository for the new Prescription Drug Repository program. She noted that doing so may provide an incentive for pharmacies and health centers to apply to be drop off sites. Mr. Taylor added that the grant would be used to partially fund pharmacist staff required to deal with the inventory requirements of the Drug Repository Program that would need to be maintained by MedBank.

Motion: Alland Leandre moved to award a \$25,000 grant to MedBank for support of the Prescription Drug Repository Program. Michael Souranis seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

Nurse-Midwife Formulary

The Board of Nursing submitted a copy of the Nurse-Midwife Formulary that would allow nurse-midwives to dispense specific medications to their patients. The Formulary has been submitted for review and approval by both the Board of Pharmacy and the Board of Physicians. The Board of Physicians reviewed the Formulary in March. The list is now submitted for the Board’s consideration. The Board of Nursing reviewed the list and did not make any changes. The list provides classes of drugs rather than the names of specific drugs.

Rodney Taylor volunteered to review the Formulary and make recommendations to the Board. Rodney Taylor will be permitted to make recommendations without authorization from the Board should an immediate response be required prior to a Board meeting.

Donald Taylor mentioned that the Board also has representation on the Nurse Dispensing Formulary Committee that is responsible for the list of prescription drugs that nurses are allowed to dispense at local health clinics. Rodney Taylor agreed to also represent the Board on that Committee.

Motion: David Chason made a motion to appoint Rodney Taylor to staff the Midwife Formulary and Nurse Dispensing Formulary Committees, and that he also be approved to make decisions regarding the formularies if an immediate response is required before consulting with the Board. Mayer Handelman seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

Meeting with Janet Nugent, Deputy Director of Personnel Services Administration

LaVerne reported that Jennifer James, who was under consideration for the Pharmacist Compliance Officer position, did not accept the position. Ms. Naesea met with Janet Nugent to discuss options for future recruitment as a result of the difficulty the Board has experienced in filling that position. Ms. Nugent provided Ms. Naesea with several options that were to be outlined during the Board Administrative session.

Division of Drug Control Report

Ms. Naesea provided the monthly report from the Division of Drug Control: There were 74 annual pharmacy inspections; 7 pharmacy opening inspections; and 5 closing inspections performed during the month of July 2007.

Ms. Naesea announced that the Board is planning a farewell dinner for former Board Commissioners. The dinner is tentatively planned at Liberatore's Restaurant on September 19th. She invited guests from the Public Meeting to contact Summar Goodman, Public Information Officer, for details.

V. PEAC (Pharmacist Education and Assistance Committee) – Gill Cohen

Gill Cohen reported that PEAC's caseload consists of 13 cases, of which 2 are pharmacy students. PEAC received 32 urine results with no positives. One new case was added since the last report. He invited meeting participants to attend PEAC's annual seminar on October 18th at Riderwood Village in Silver Spring, Maryland. The seminar is entitled "*The Bottom Line on Addiction and Recovery. Practical Lessons and Guidance for Pharmacists, Colleagues and Employers*". Mr. Cohen also reported that the fundraising for PEAC is progressing.

VI. Legislation and Regulation Manager – LaVerne Naesea for Anna Jeffers

A. Legislation

A courtesy copy of the Drug Therapy Management (DTM) legislative proposal was sent to the original sponsors on August 2, 2007.

B. Regulation Updates

Reinstatement and Pharmacy Technicians

Responses to the 11 comments were sent July 24, 2007. The re-proposals were submitted to the DHMH on August 1, 2007. The regulations are expected to be published on September 28th in the *Maryland Register*. There will be a 30-day public comment period following publication.

Sterile Pharmaceutical Compounding

The “Notice of Final Action” was signed on August 6, 2007, and the final regulations are anticipated to be published September 10, 2007. The effective date will be 10 days after publication.

Licensing of Wholesale Prescription Drug or Device Distributors

The Wholesale Distributor SB 759 Workgroup made final recommendations and approved the draft regulations on August 13, 2007. The draft regulations are to be reviewed by the Practice and Licensing Committees, and are expected to be submitted to the Board for final approval on September 19, 2007. At the August Meeting, the Task Force began planning the survey on the availability of electronic pedigrees.

VII. Administration and Public Support – Patricia Gaither

A. Personnel Update

Ms. Gaither reported that she has received approval of the Board’s freeze exemption request for the Office Secretary III position. Interviews for that position will begin within the next two weeks. Ms. Gaither stated that she expects to receive approval of the freeze exemption request for the Health Occupation Investigator position in the near future.

Ms. Gaither reported that the Board has submitted job descriptions for four (4) pharmacy inspectors and one pharmacist supervisor inspector for review by the personnel classification unit. The five (5) inspectors will conduct inspections of pharmacies and distributors once responsibilities are transferred to the Board from the Division of Drug Control.

B. Public Information Officer Report – Summar Goodman

News Article – “Maryland to test flu preparedness”

Ms. Goodman noted that a news article was included in the Board packet from the “Examiner” on the emergency preparedness drill held from July 31st thru August 2nd. The Board participated in the drill on August 1st. Donald Taylor and Cynthia Anderson represented the Board of Pharmacy. It was stated that the pharmacy contingent performed well during the drill. It is expected that the pharmacists’ role would be expanded during an actual event to include final verification of medications.

Emergency Preparedness Task Force

Ms. Goodman reported that the Board’s Emergency Preparedness Task Force would host a Phase I volunteer training program on Sunday, October 28th, from 7:30 am until 1:00 pm at the Raddisson-Cross Keys Hotel. Announcements will be mailed within two (2) weeks. New volunteer identification photographs will be taken during the event.

Maryland ASCP 14th Annual Conference

Cynthia Anderson, Shirley Costley, and Summar Goodman attended the ASCP conference. Summar Goodman staffed a vendor booth and Cynthia Anderson made a presentation on the subject of pharmacy technician program.

National Pharmacist Month

The Board is planning an event to celebrate American Pharmacists’ month in October. Howard Schiff noted that the Pharmacy Coalition would display a banner at Light and Pratt Streets during the month of October for American Pharmacists’ Month. Howard Schiff invited the Board to attend a meeting Wednesday, August 29th, 6 pm at the Kelly Building to discuss plans for American Pharmacists’ month.

VIII. Management Information Services – LaVerne Naesea for Tamarra Banks

In-House Database Implementation

Ms. Naesea reported on behalf of Ms. Banks. The Towson contract should be submitted August 24th for Ms. Naesea’s signature. The contract will then be forwarded to the State Procurement office for final approval.

Hardware/Software

Tamarra will coordinate with other Boards' IT staff members to develop a combined list of stolen prescription pads.

HIPBD

Ms. Naesea reported that Steven Kreindler has begun entering data regarding pharmacists under Board orders into the HIPBD database daily in order to bring reporting up-to-date.

On-line Renewal Database

The Board operations have been affected because two of its servers had broken down. Staff members were unable to view certain on-line renewals. In the interim, on-line information has been entered manually by Board staff. MIS projects that the problems will be fixed within the next two (2) weeks. Ms. Naesea apologized for any inconvenience to those affected by the server problems.

Division of Drug Control/Inspections

MIS is attempting to obtain copies of all inspections forms to update them in the database system. Ms. Naesea stated that Ms. Banks would be contacting Committee Chairs for the most up-to-date inspection forms.

It is anticipated that the Board will have an automated payment system in operation for establishments by 2008.

Secure Website

A secure website, available only to members, is being developed so that Board and staff can post confidential documents. Ms. Banks will distribute instructions on how to access the website. Ms. Naesea is hoping to include minutes and Board packet attachments on the secure website once it is refined and tested.

IX. Committee Reports

A. Practice Committee – Cynthia Anderson for David Chason

1. Constituent Questions and Responses

- a. Michael (by e-mail) wrote to the Board concerning dispensing a generic medication where part of the prescription is from one manufacturer and the remaining portion is from a second manufacturer.

Following discussion of the proposed response it was recommended that the letter be referred back to Practice Committee for reconsideration.

Motion: Cynthia Anderson recommended to defer a Board vote and refer the letter from Michael (by e-mail) back to the Practice Committee. David Chason seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

- b. Elisa Muller wrote concerning whether a multi-dose method of packaging prescription drugs, to be dispensed to a patient, is allowed in Maryland.

The Practice Committee recommended that if the label on the packaging contains all of the items that are required for prescription medications in Maryland for each medication included in the multi-dose packet, then this type of packaging would be in compliance with the Maryland law.

Motion: Harry Finke, Jr. moved to accept the Practice Committee letter as amended. Alland Leandre seconded the motion.

Board Action: The Board voted unanimously to approve the Practice Committee recommendation with the amendment “If one medication is discontinued, or there is a change in regimen, then the entire card should be returned to the pharmacy.”

- c. Bill Vaughan of OHCQ contacted the Board concerning whether there are regulations that would prohibit a nurse (RN or LPN) from removing a quantity of medication from a properly dispensed and labeled supply for a resident at a long term care facility (LTC) and then providing that quantity of medication along with written instructions to the resident and/or caregiver to use during an unscheduled leave of absence (LOA).

The Practice Committee’s recommended response was that a physician may not delegate the act of dispensing to a nurse in a Long Term Care facility. If a resident is being discharged or going home for a visit from a LTC facility, the medications may be labeled and dispensed by the pharmacy. If the physician has ordered a resident to be discharged with medications, the medications should be labeled correctly and an acknowledgement received from the resident that the medications may not be in a child proof container.

Maryland law does not provide for the practice of nurses dispensing medications to residents on Leave of Absence. If a LTC facility is compelled to accommodate a resident, then the LTC facility must have appropriate policies and procedures in place to ensure proper labeling and clear directions. The safety of the resident should be the primary concern. Whenever possible, LOA medications should be dispensed by a pharmacy as previously indicated.

The Board amended the response by adding the legal citations, 12-102 (c) and 14-306.

Motion: Mayer Handelman moved to accept the Practice Committee's letter with amendments. Rodney Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the letter with the amendments.

- d. Lee M. Cappucci, Long Term Care, contacted the Board concerning Maryland's policy for the return of drugs after 24 hours of discharge of a long term care (LTC) resident.

The Practice Committee's recommended response was that the Code of Maryland Regulations (COMAR) 10.34.10.07 permits a pharmacist to accept the return to a properly labeled and properly sealed manufacturer's package or individual unit dose of a drug or device that the pharmacist determines to have been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the sale of the drug or device and its return to the pharmacy. Once a resident leaves a LTC facility with medications, the pharmacy cannot ensure the integrity of those medications.

It was recommended that Ms. Cappucci be advised to also consult with the Office of Health Care Quality.

Motion: Rodney Taylor moved to accept the Practice Committee's letter as amended. Mayer Handelman seconded the motion.

Board Action: The Board voted unanimously to approve the Practice Committee's letter with the amendment.

- e. Danna Kauffman of LifeSpan wrote to the Board concerning clarification on how long-term care (LTC) communities should handle short term leave of absence such as an afternoon, when prior notice is not given thereby, not allowing sufficient time for the pharmacist to package and label necessary medications.

The Practice Committee recommended the following response. Maryland law does not provide for the practice of Long Term Care centers or nurses dispensing medications to residents on LOA. If a LTC leave of absence is compelled to accommodate a resident, then the LTC community must have appropriate policies and procedures in place to ensure that all medications properly labeled and directions are provided. The safety to the resident should be the primary concern. Whenever possible, LOA medications should be dispensed by a pharmacy if sufficient time is available for a pharmacist to package and label the medications.

Motion: David Chason moved to accept the Practice Committee's letter as written. Mayer Handelman seconded the motion.

Board Action: The Board voted unanimously to approve the Practice Committee's letter.

- f. Cherokee Layson-Wolf, Pharm. D., CGP, contacted the Board concerning whether a patient prescribed a CIII-CV Controlled Dangerous Substance, with 5 refills, may only receive 5 refills (or partial fills) in 6 months regardless of the remaining amount prescribed or whether a patient may receive refills (or partial fills) until the total quantity prescribed has been dispensed within 6 months.

The Practice Committee's recommended response was that when a patient is prescribed a CIII-CV CDS with 5 refills, the patient might receive refills (or partial fills) until the total quantity prescribed has been dispensed as long as it is within 6 months. The proposed response referred her to the Code of Maryland Regulations (COMAR) 10.19.03.09C, regarding partial filling of prescriptions, which states:

- B. Partial Filling of Prescriptions (21 CFR § 1306.23). The partial filling of a prescription for a controlled dangerous substance listed in Schedule III, IV or V is permissible, provided that:
 - (1) Each partial filling is recorded in the same manner as a refilling;
 - (2) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
 - (3) No dispensing occurs after 6 months after the date on which the prescription was issued.

It was recommended that the Practice Committee's recommendation be published in the next Newsletter.

New Action Item: Summar Goodman to have response published in next Newsletter.

Motion: David Chason moved to accept the Practice Committee's letter as written. Rodney Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the Practice Committee's letter.

- g. Eric Huber contacted the Board concerning the appropriateness of dispensing insulin pens (NovoLog) and needle caps (box of 100) to patients at the time of discharge. The pens will be the same pens that they had been using when they were an inpatient.

The Practice Committee's recommended response was that if the insulin pens are the result of a physician's discharge order and are properly labeled and dispensed by the hospital pharmacy at discharge, Maryland law and regulations do not impose any further restrictions.

Motion: David Chason moved to accept the Practice Committee's letter as written. Harry Finke, Jr. seconded the motion.

Board Action: The Board voted unanimously to approve the Practice Committee's letter.

2. Prescription Signatures Options Chart

The chart was submitted to the Board of Physician's Practice Committee on August 3, 2007. The Board of Physicians, Board of Nursing, Board of Dental examiners and other relevant Boards will be asked to notify all prescribers of the chart through mailings or their respective newsletters.

B. Licensing Committee – Michael N. Souranis

Mr. Souranis reported the statistics for the Month of July. The number of pharmacists scheduled to renew in July was 385 compared to 319 in July last year. The total number of pharmacists that renewed in July was 352 of which 265 renewed online. The number of non-renewed pharmacists in July was 33, compared to 28 in July 2006. Ms. Costley, Licensing Supervisor, stated that notification is sent to those who do not renew after verification and that appropriate notifications and electronic transmissions have been completed.

New establishments:

Distributors: 10; in-state 0; out-of-state 3; Total 13

Pharmacies: Resident 4; New 11; Non-Resident 4; Pharmacy 2/Waiver - 1 Total – 20

Closed Establishments

Distributors: In-state 0; Out-of-State – 0

Full Service Pharmacies: 0

Waiver Pharmacies: 2

Ms. Naesea recommended that Waiver Pharmacy applications received should be reviewed by the Licensing Committee for approval. Mr. Souranis stated that the issue would be addressed at the next Licensing Committee meeting.

Donald Taylor distributed the new draft Community Pharmacy inspection form for review and consideration for approval by the Board. It was suggested that N/A (not applicable) be deleted from most questions on the form. David Chason stated that the removal of N/A should also apply to the Hospital form.

Motion: Harry Finke, Jr. moved to accept the Community Pharmacy inspection form with amendments. Rodney Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

The Long Term Care draft inspection form was distributed and reviewed by the Board. It was suggested that the format remain the same with the following content changes:

- page 2, #13 – the “W”
- Page 3, #19 – delete Donald Taylor’s notation
- Page 4, #30 – delete the word “please” and replace with the word “must”
- Page 4, #35 – add lines and use separate sheet if necessary

Motion: Alland Leandre moved to accept the Long Term Care inspection form with amendments. Michael Sournais seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

C. Long Term Care Task Force – Mayer Handelman

Mr. Handelman reported that at the ASCP meeting there was discussion about proposed assisted living regulations that would require pharmacist review of medication profiles for patients receiving 9 medications or more on a three or six (6) months cycle. It is felt that the Office of Health Care Quality is leaning towards a six (6) months cycle.

X. Informational

Donald Taylor shared with the Board current informational Pharmacy Issues.

1. 2003 Medicare Modernization Act (MMA) Statement by Secretary Leavitt proposed rule indicates that after January 1, 2009, prescription forms can NOT be sent by computer generated faxes. Prescriptions may still be sent via stand alone fax machines.

2. Tamper Resistant Rx Pads

CMS deadline 10-1-2007 – To be considered tamper resistant by CMS, blanks must contain at least one of the following:

(A) one or more industry recognized features designed to prevent unauthorized copying of completed or blank Rx forms; (B) one or more industry – recognized features designed to prevent the erasure or modification of information written by the prescriber; (C) One or more industry – recognized features designed to prevent the use of counterfeit Rx forms.

After October –1, 2008, all of the above must apply.

The Rule Does Not Apply to the Following:

- a. Electronic, verbal or faxed prescriptions when a managed care entity pays for the Rx. b. May still use non-compliant forms if a verbal Rx, faxed, electronic, or compliant prescription is provided within 72 hrs. At this time 76 health care organizations have urged Secretary Leavitt to delay the implementation date.
3. Strike Force Prosecutions & Demonstration Project – HHS
This applies to providers of INFUSION therapy;
All providers in South Florida must re-apply to be qualified Medicare Infusion therapy providers.
4. It has been reported that pain medication use has doubled from 1997 to 2005 as reported by the Associated Press.

New Action Item: The Board will write a letter to the Attorney General and NABP concerning “Rogue” Internet Pharmacies.

The Board adjourned the Public Meeting at 11:30 am, and immediately thereafter convened a Closed Public Meeting for purposes of discussing personnel issues. The closed Public Meeting was adjourned at 12:00, and immediately thereafter an Administration Session was opened to discuss confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.